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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,958	10/31/2003	Michael N. Helmus	ECV-5589 DIV	5993
30452	7590	08/31/2006	EXAMINER	
EDWARDS LIFESCIENCES CORPORATION LEGAL DEPARTMENT ONE EDWARDS WAY IRVINE, CA 92614			PELLEGRINO, BRIAN E	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 08/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/700,958		HELMUS ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Brian E. Pellegrino		3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 65-85 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 65-85 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>10/31/03</u>  | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Drawings*

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "reservoir located on the sewing ring" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 82 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 82 recites the limitation "said microcapsule" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 65-70,79-82,84 are rejected under 35 U.S.C. 103(a) as being unpatentable over McDaid et al. (WO 9630060) in view of Ragheb et al. (6299604). McDaid et al. disclose a heart valve prosthesis with therapeutic capabilities via a sewing ring having the agent incorporated into the sewing ring, page 4, lines 30-32, page 6, lines 31-33. McDaid also discloses the agent can be "encapsulated" or trapped or in a "reservoir" which is a polymer coating, page 8, lines 6-11. McDaid additionally discloses the sewing ring is made of a polymer, page 4, lines 34-36. However, McDaid fails to disclose the therapeutic agent is a antimicrotubule agent. Ragheb et al. teach that an

antimicrotubule agent can be incorporated onto a heart valve prosthesis to prevent hyperplasia, col. 3, lines 54,55,63,66, col. 6, lines 56,57,60, col. 9, lines 27,28,42, col. 14, lines 35,36,47-54. Ragheb also teaches the antimicrotubule agent can be a taxane derivative, col. 9, lines 12-16,47-49. Ragheb additionally teaches that the agent can be microencapsulated, col. 24, lines 6-8. It would have been obvious to one of ordinary skill in the art to incorporate an antimicrotubule agent on the sewing ring as taught by Ragheb et al. in the heart valve prosthesis of McDaid et al. such that it prevents tissue hyperplasia that can cause failure of the valve.

Claims 71-73,75,76,83 are rejected under 35 U.S.C. 103(a) as being unpatentable over McDaid et al. (WO 9630060) in view of Ragheb et al. '604 as applied to claim 69 above, and further in view of Tweden et al. (5895419). McDaid et al. as modified by Ragheb et al. is explained above. However, McDaid in view of Ragheb fail to disclose the sewing ring is a made of fabric. Tweden et al. teach a sewing ring formed of a fabric such that it can have a therapeutic agent incorporated therein, col. 4, lines 32-37. Tweden also teaches that the fabric for the sewing ring can be a polyester or polyethylene, col. 5, lines 34,35. It would have been obvious to one of ordinary skill in the art to utilize a fabric as the sewing ring as taught by Tweden et al. with the heart valve prosthesis of McDaid as modified by Ragheb such that it permits greater impregnation of the therapeutic material into the ring that is intended to treat the tissue.

Claims 74,77,78 are rejected under 35 U.S.C. 103(a) as being unpatentable over McDaid et al. (WO 9630060) in view of Ragheb et al. '604 and Tweden '419 as applied to claims 72,76 above, and further in view of Silvestrini et al. (4834755). McDaid et al.

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as modified by Ragheb et al. is explained above. However, McDaid in view of Ragheb and Tweden fail to disclose the fabric is nylon or that it is a combination. Silvestrini et al teach that nylon and combination yarns that include a polyester and polypropylene are used for a fabric prosthesis, col. 5, lines 48-50, 61-64. Silvestrini also discloses the fabric can be used for a heart valve prosthesis, col. 8, lines 1-22. It would have been obvious to one of ordinary skill in the art to utilize a nylon or combination yarn for the sewing ring fabric as taught by Silvestrini et al. with the heart valve prosthesis of McDaid as modified by Ragheb and Tweden such that it provides a strong material capable of withstanding the pulling placed on it while suturing to the tissue.

Claim 85 is rejected under 35 U.S.C. 103(a) as being unpatentable over McDaid et al. (WO 9630060) in view of Ragheb et al. '604 as applied to claim 84 above, and further in view of Clayton et al. (5529913). McDaid et al. as modified by Ragheb et al. is explained above. However, McDaid in view of Ragheb fail to disclose the microcapsule is a sodium alginate envelope. Clayton et al. teach that sodium alginate capsules cause the least immune response when used in the body, col. 1, lines 40-44. Clayton also teaches that the alginate material is useful in procedures involving blood and can be applied with graft material, col. 3, lines 6-8, 38-40. It would have been obvious to one of ordinary skill in the art to use sodium alginate as the microcapsule as taught by Clayton et al. with the heart valve prosthesis of McDaid as modified by Ragheb such that it causes the least immunogenic response as possible.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on Monday-Thursday from 7:30am to 5pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TC 3700, AU 3738

**BRIAN E. PELLEGRINO**  
**PRIMARY EXAMINER**

*Brian Pellegrino*